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Stout et al.

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(54) **TIP PROTECTOR SLEEVE**

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(51) **Int. Cl.**

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A61M 5/32	(2006.01)
A61F 6/06	(2006.01)
A61F 6/22	(2006.01)
A61B 17/42	(2006.01)
A61F 6/18	(2006.01)
A61B 17/12	(2006.01)
A61B 19/00	(2006.01)

(52) **U.S. Cl.**
CPC ***A61F 6/225*** (2013.01); ***A61B 17/42*** (2013.01); ***A61F 6/18*** (2013.01); *A61B 2017/1205* (2013.01); *A61B 2019/304* (2013.01); *Y10T 29/49826* (2015.01)

(58) **Field of Classification Search**
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USPC 604/528, 95.01, 263, 264, 158, 604/162–163, 164.01, 164.08; 600/101, 600/104; 128/830, 831, 840
See application file for complete search history.

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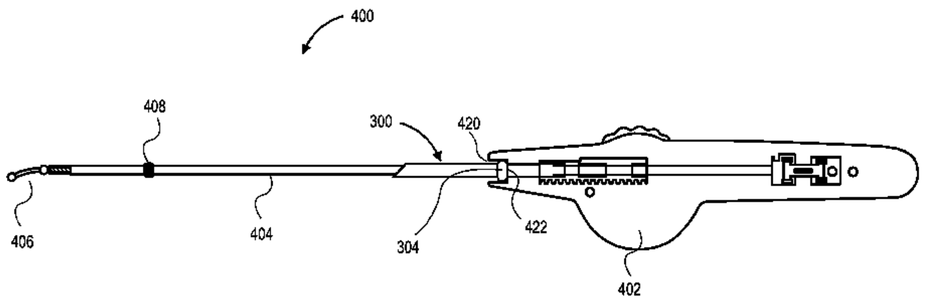
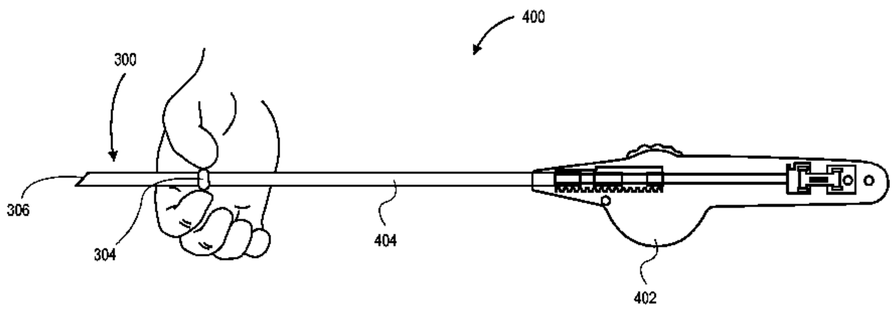
(57) **ABSTRACT**

Assemblies and methods of inserting a delivery catheter assembly into a working channel are disclosed. In accordance with some embodiments, a delivery catheter assembly is disclosed in which a tip protector sleeve is locked onto an elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath.

11 Claims, 18 Drawing Sheets





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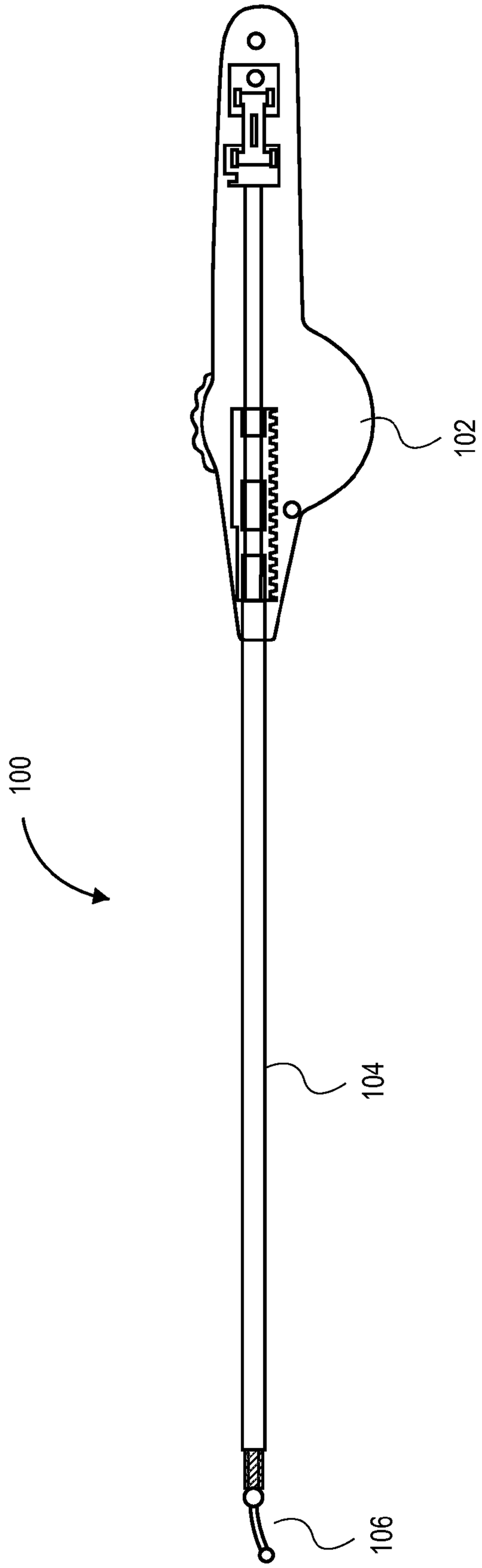

FIG. 1
(PRIOR ART)

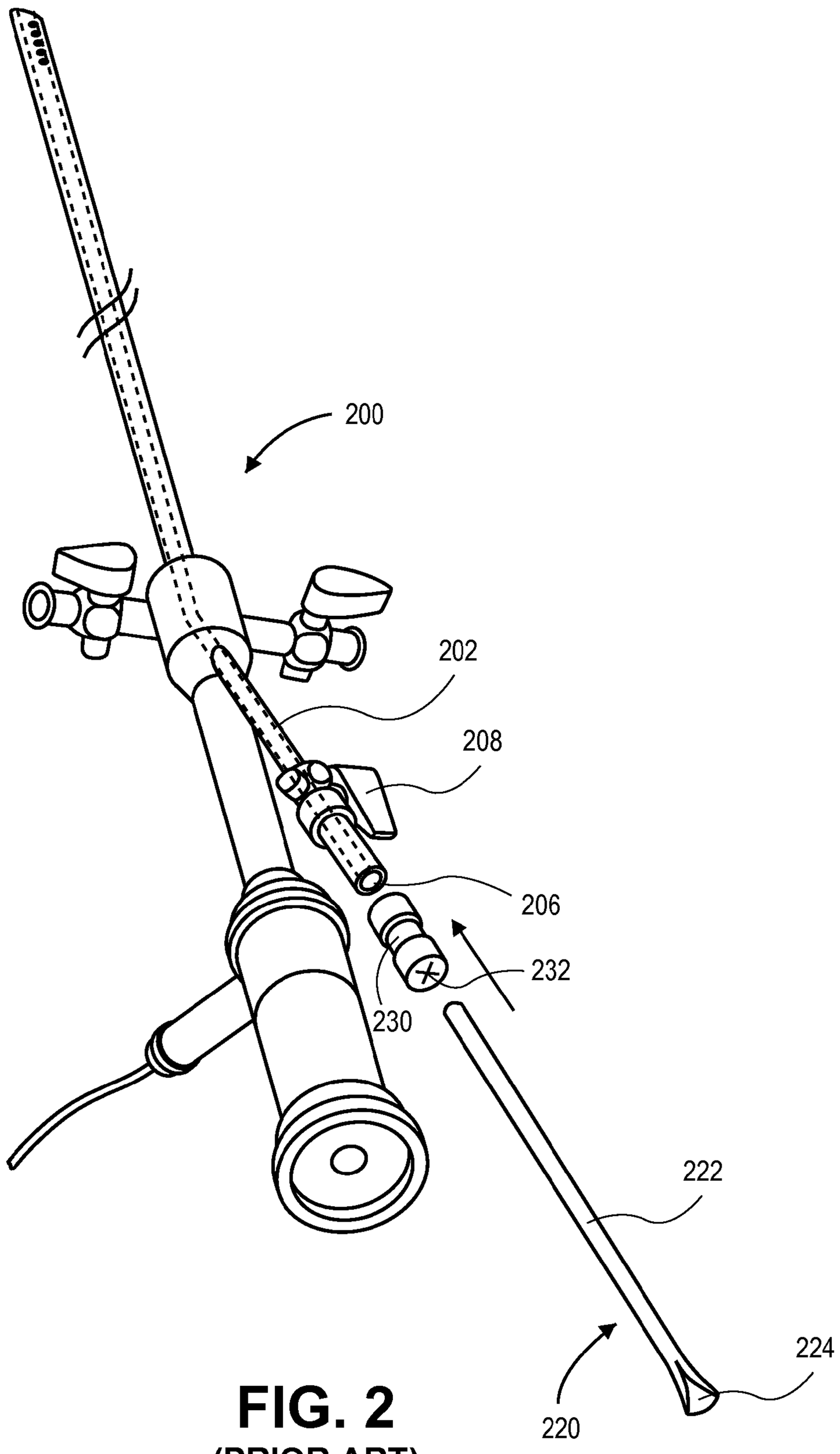

FIG. 2
(PRIOR ART)

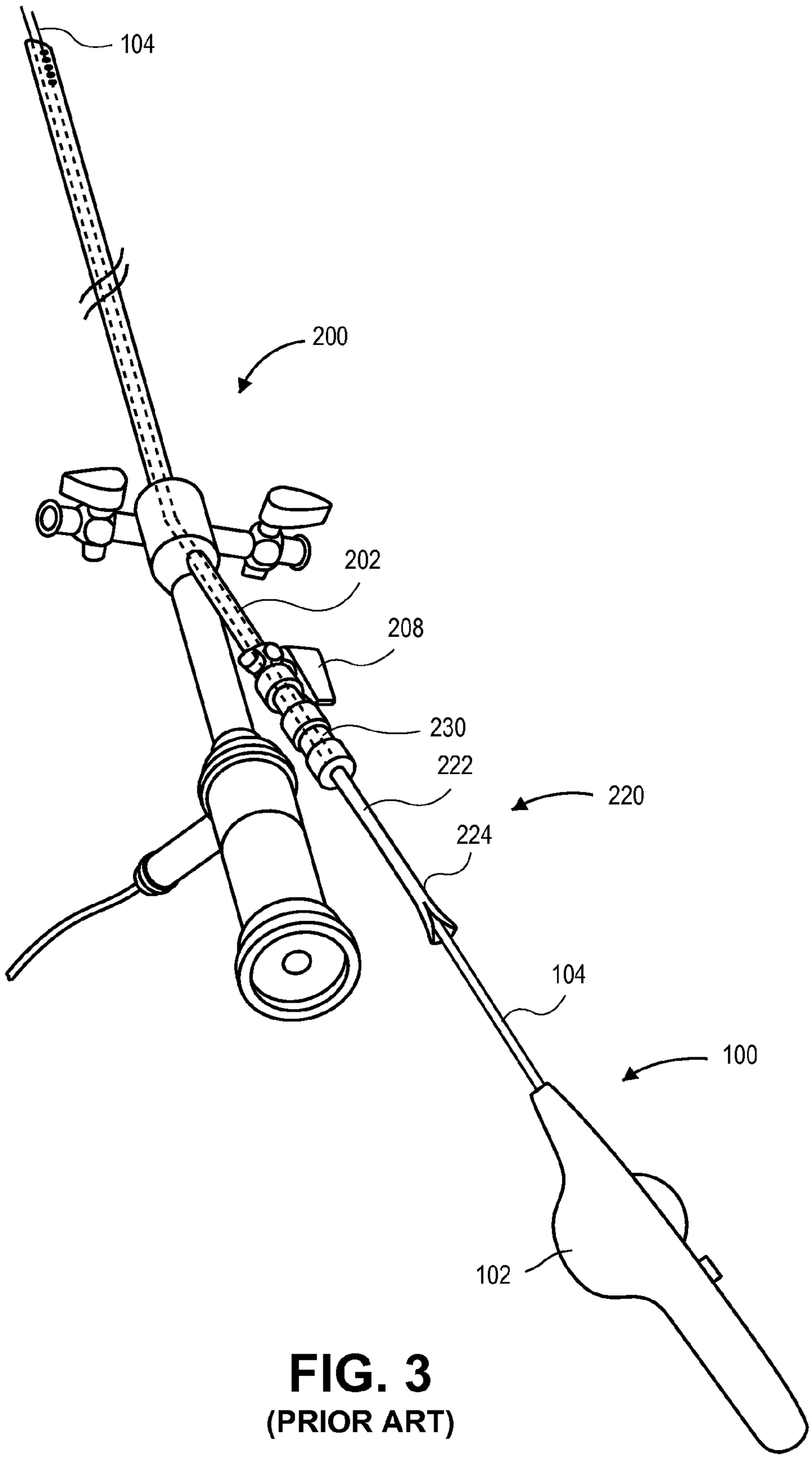

FIG. 3
(PRIOR ART)

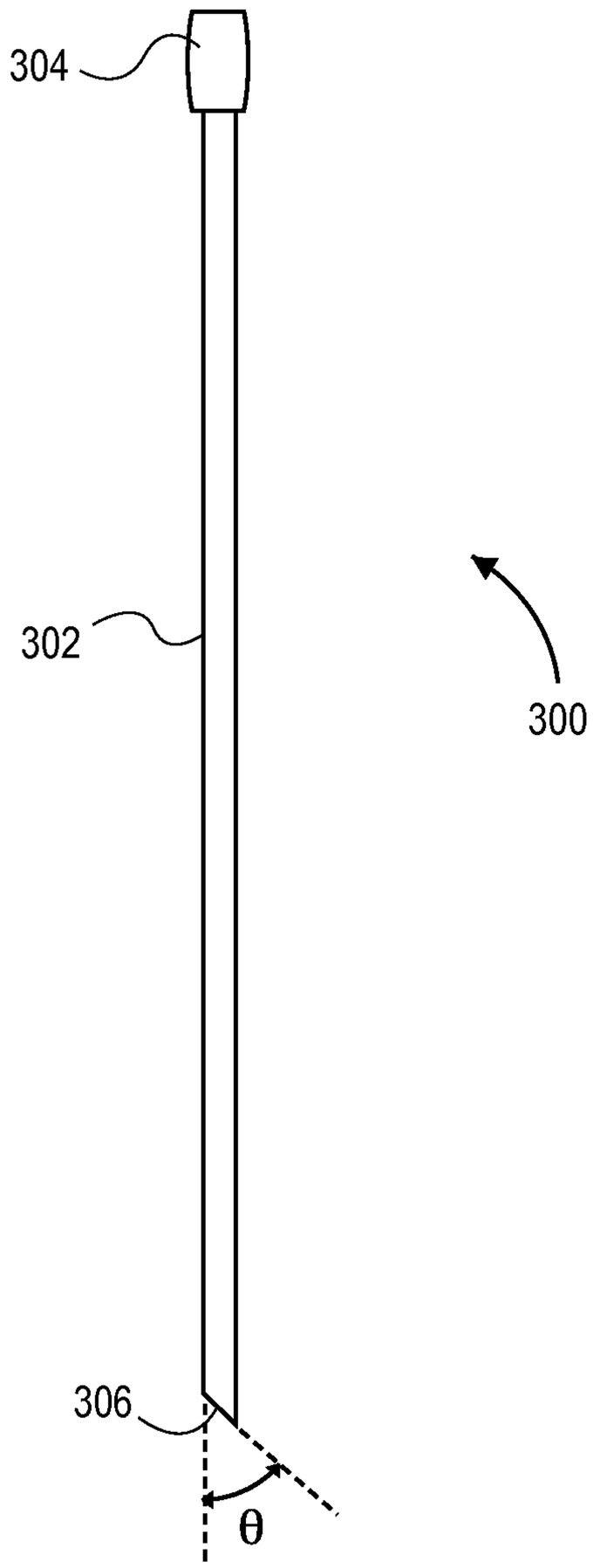

FIG. 4

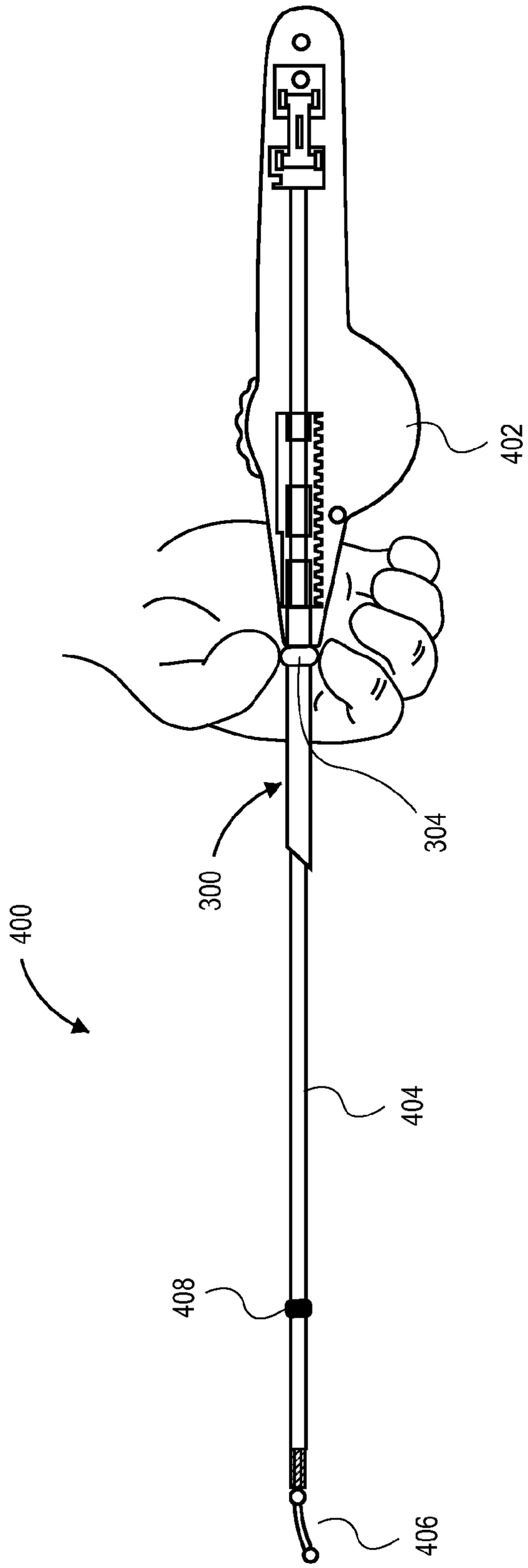

FIG. 5A

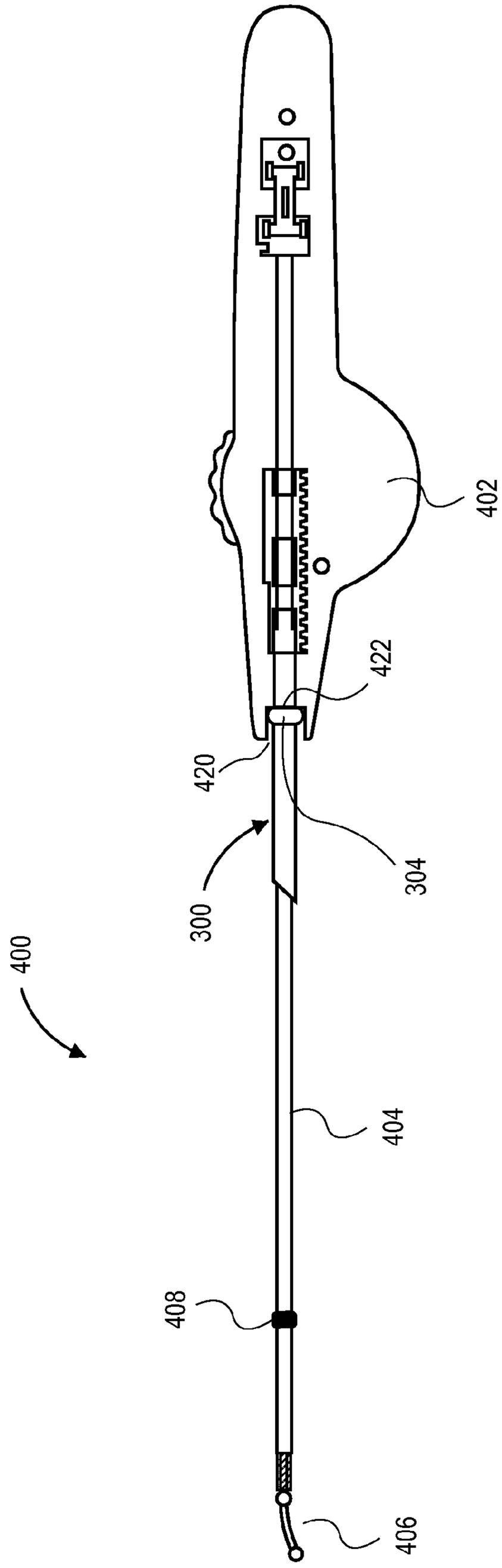

FIG. 5B

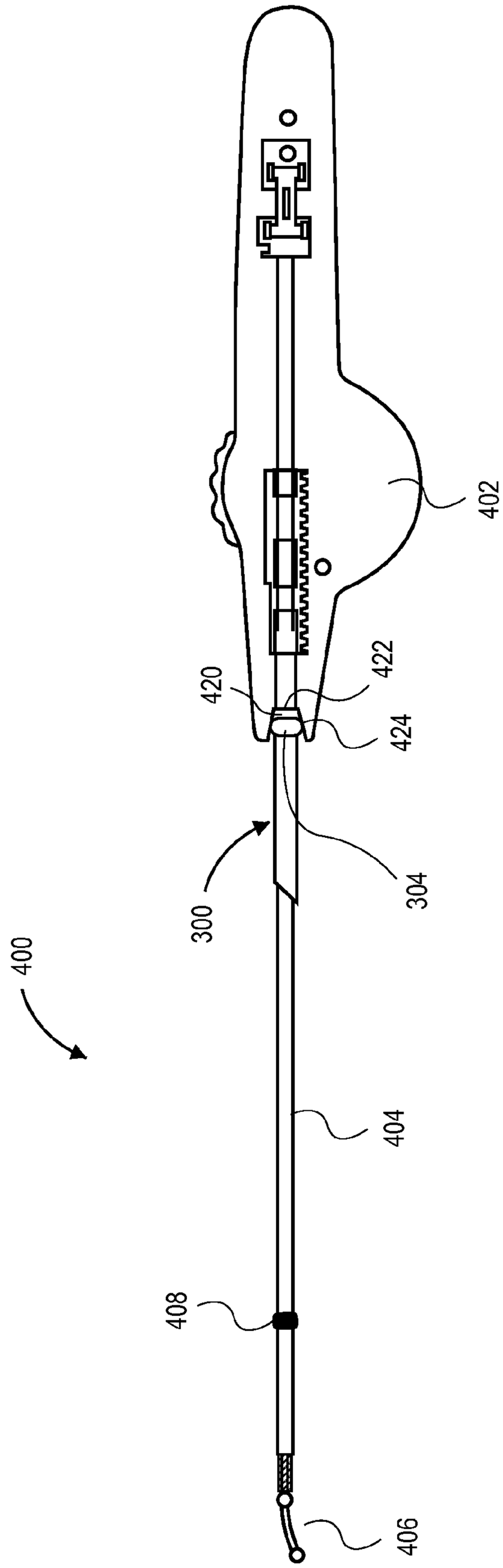

FIG. 5C

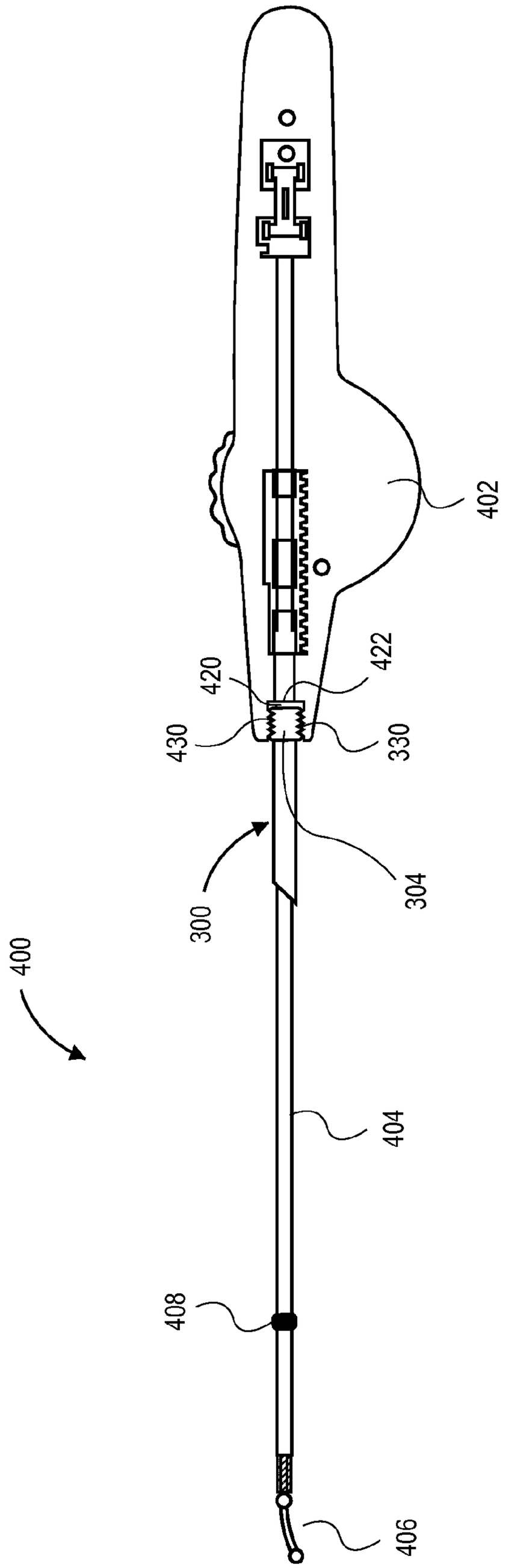

FIG. 5D

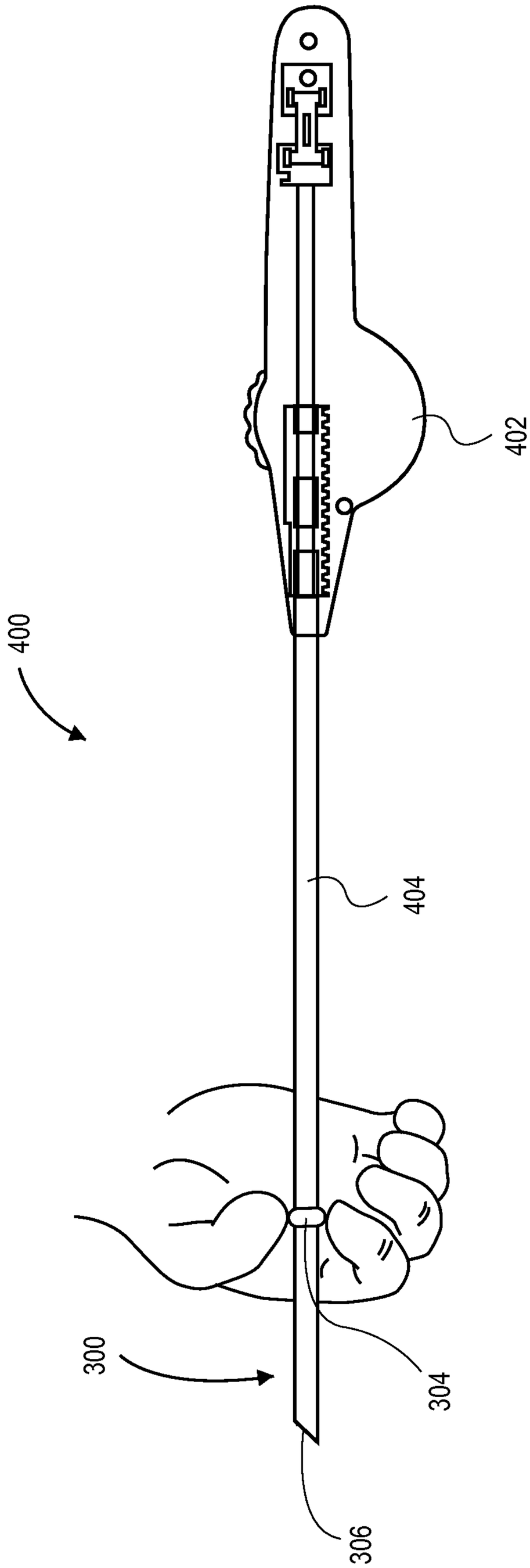

FIG. 6

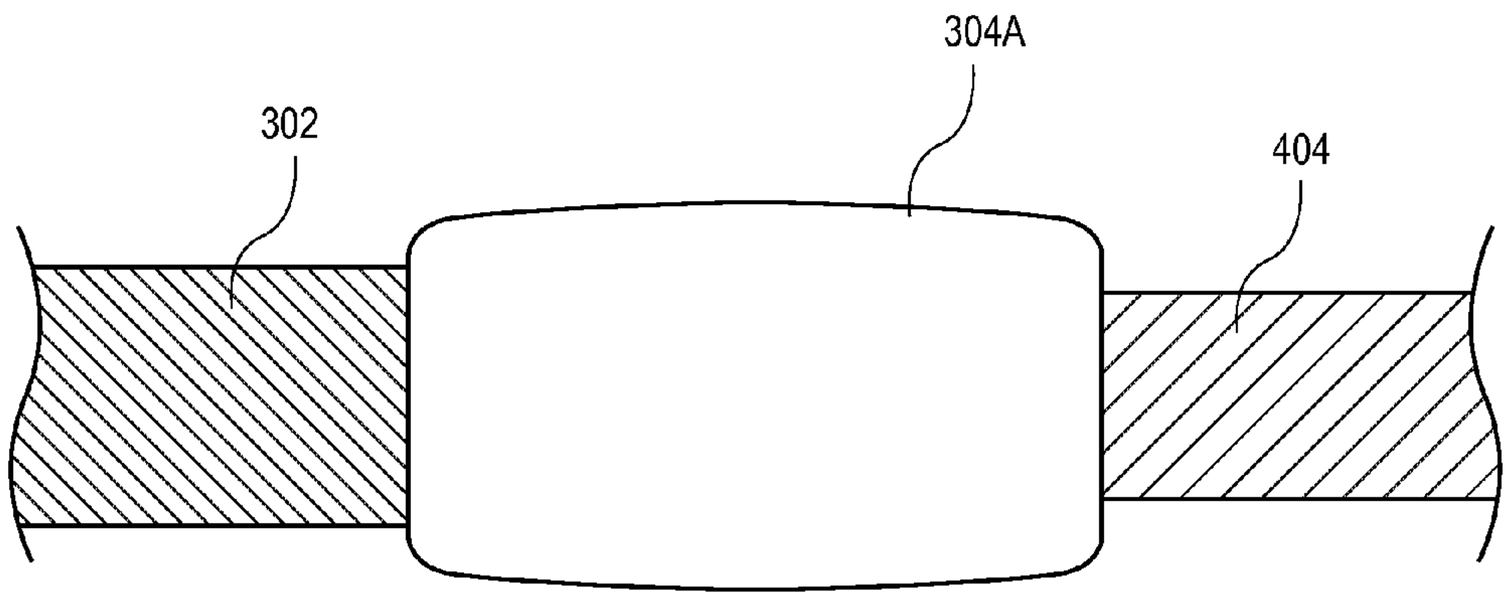

FIG. 7

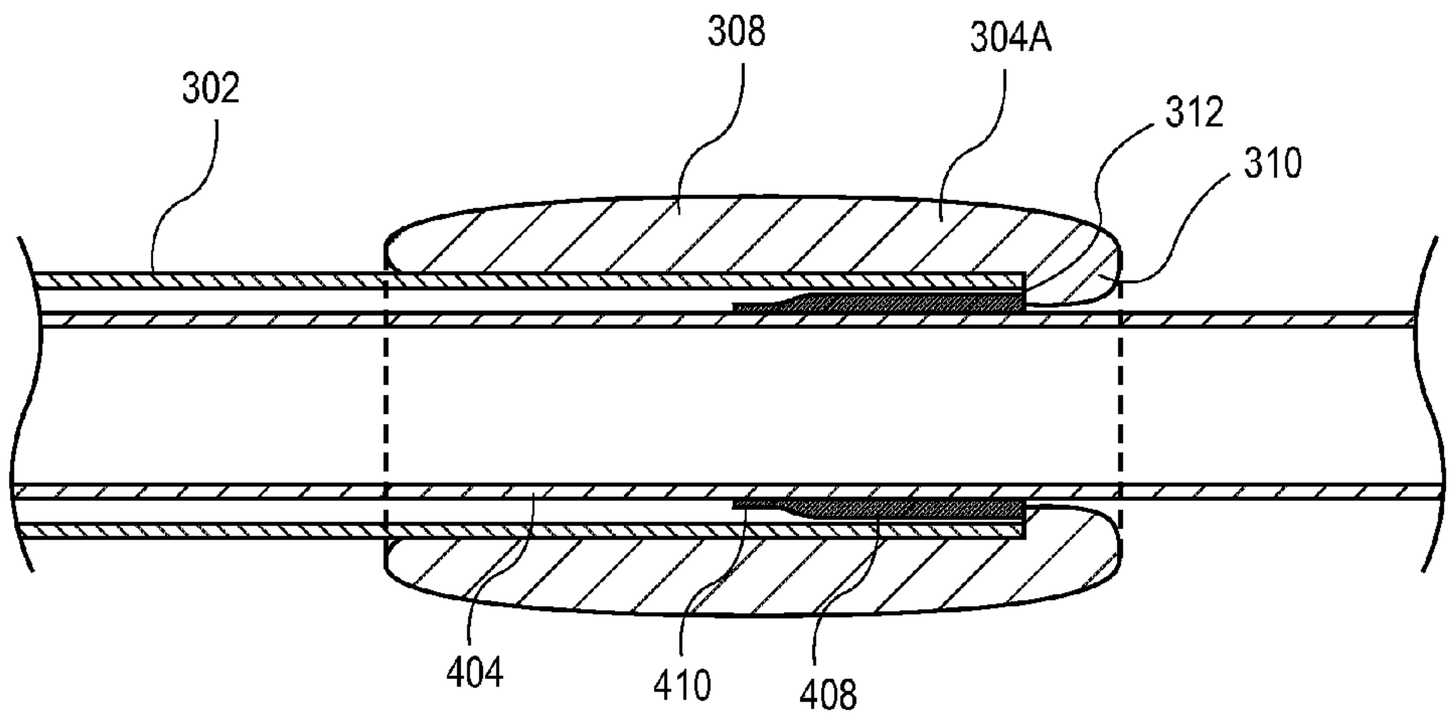

FIG. 8

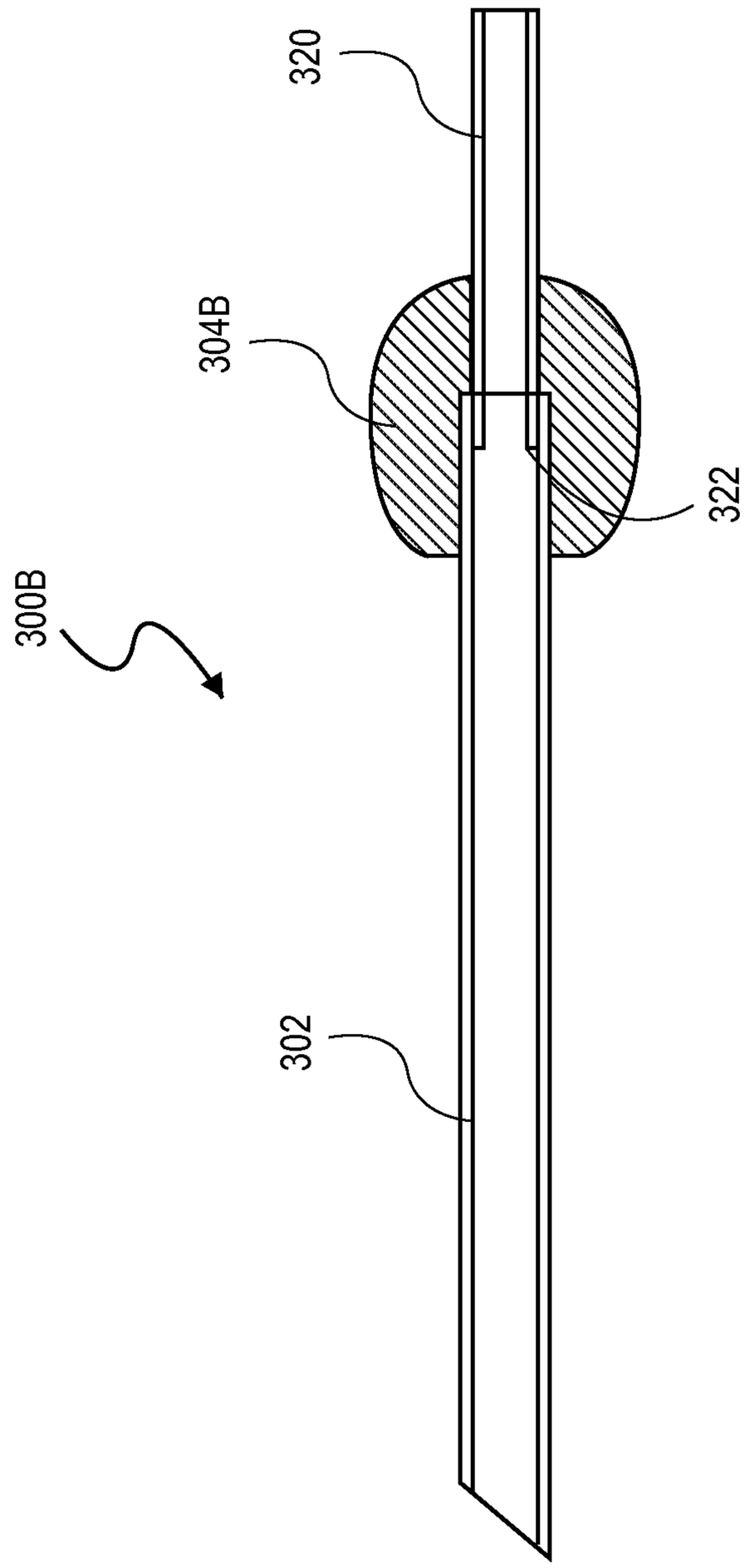

FIG. 9

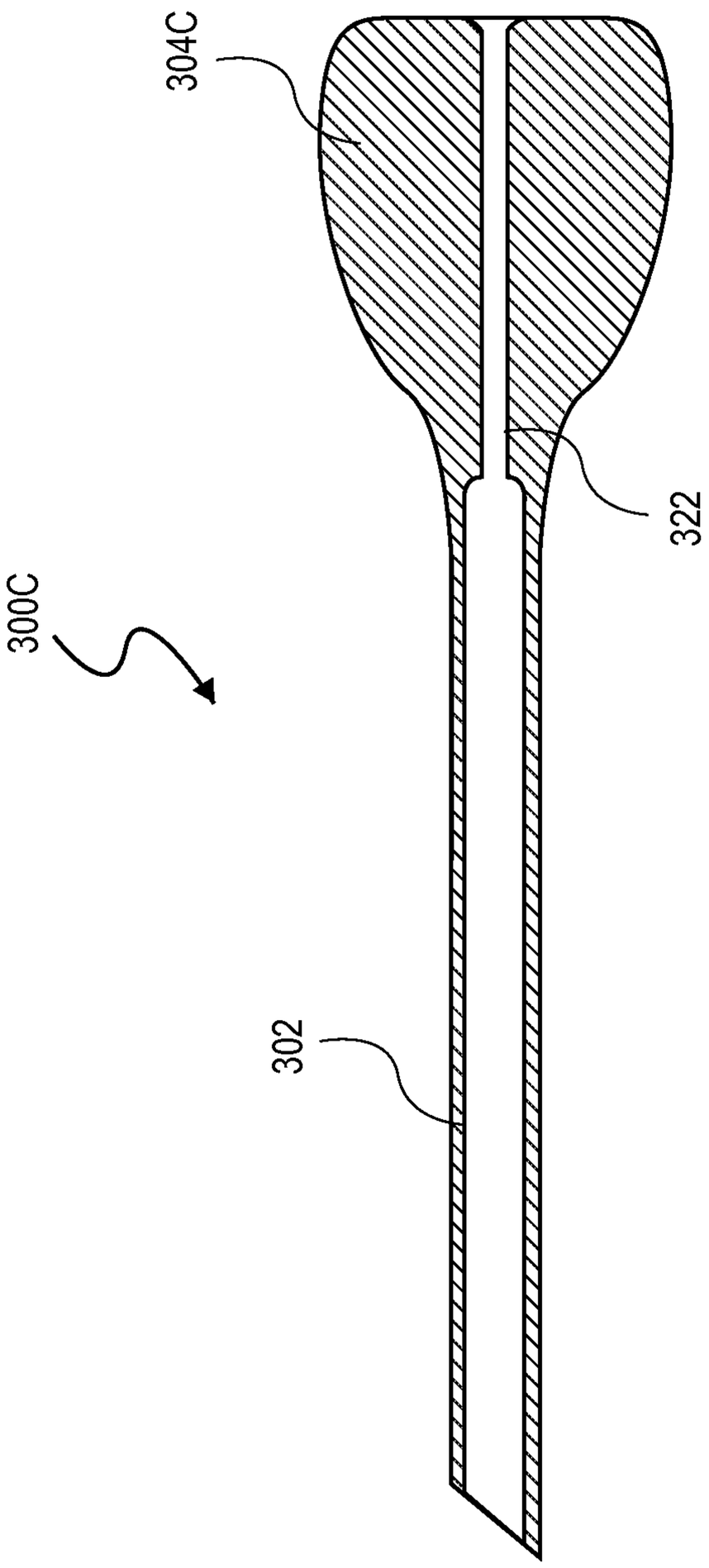

FIG. 10

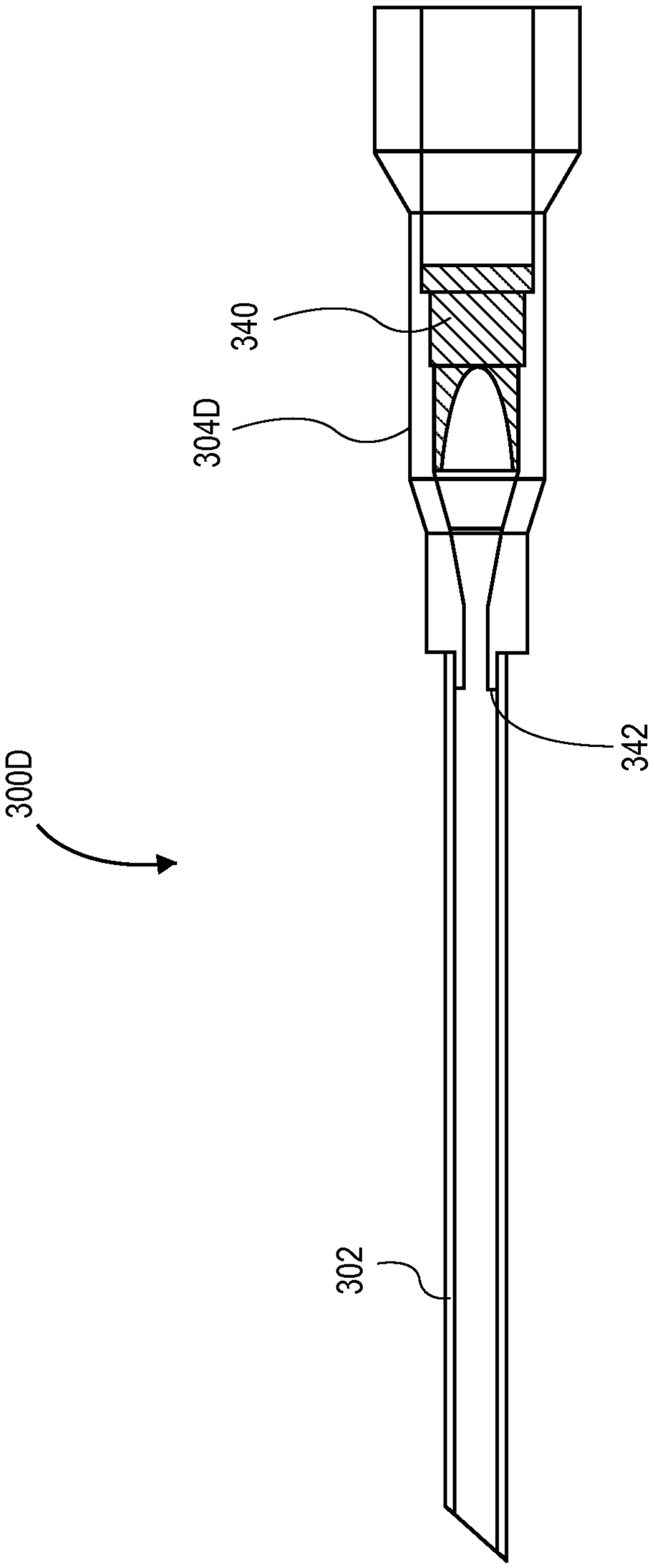

FIG. 11A

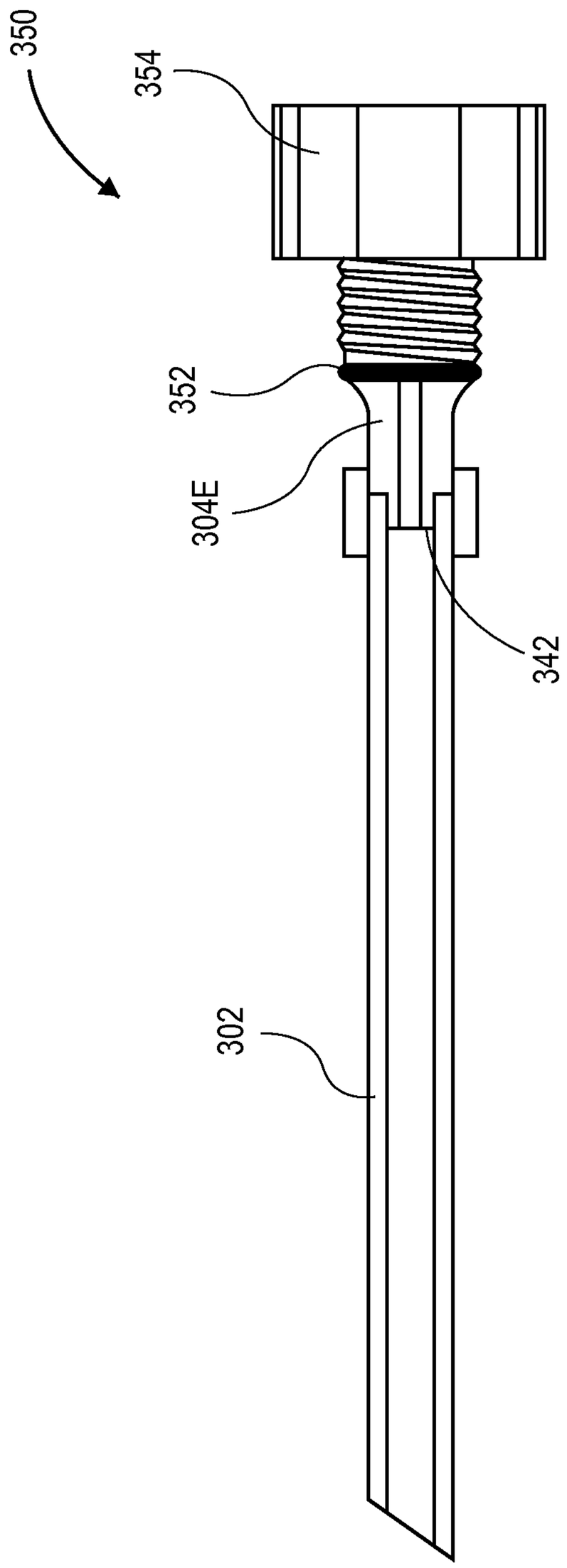

FIG. 11B

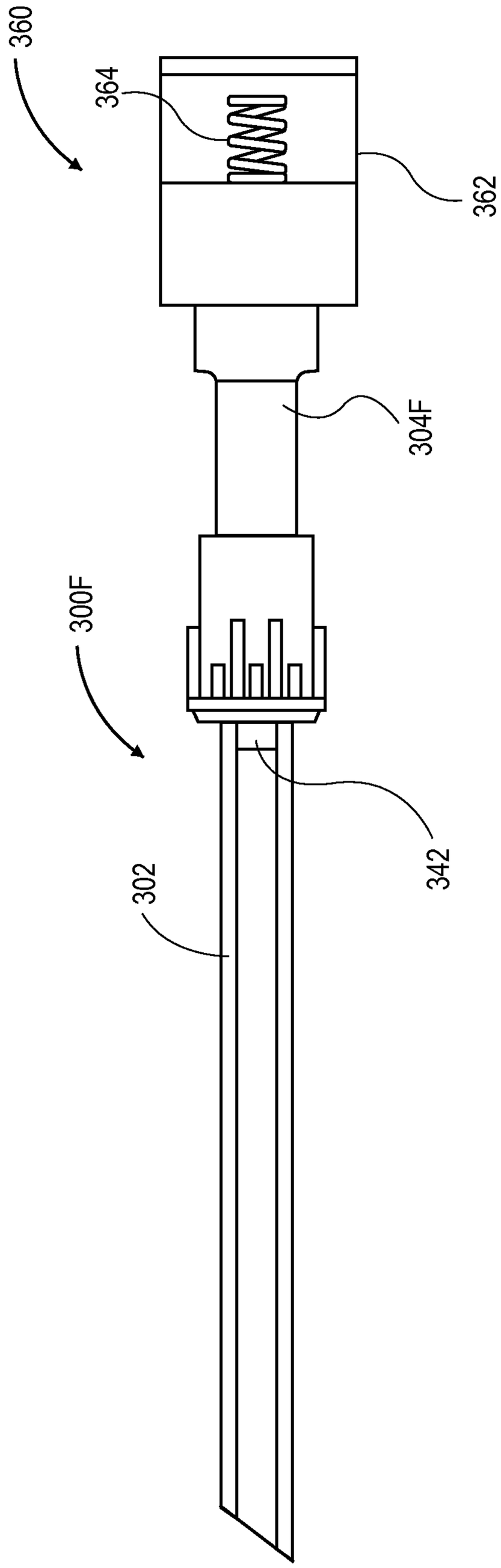

FIG. 11C

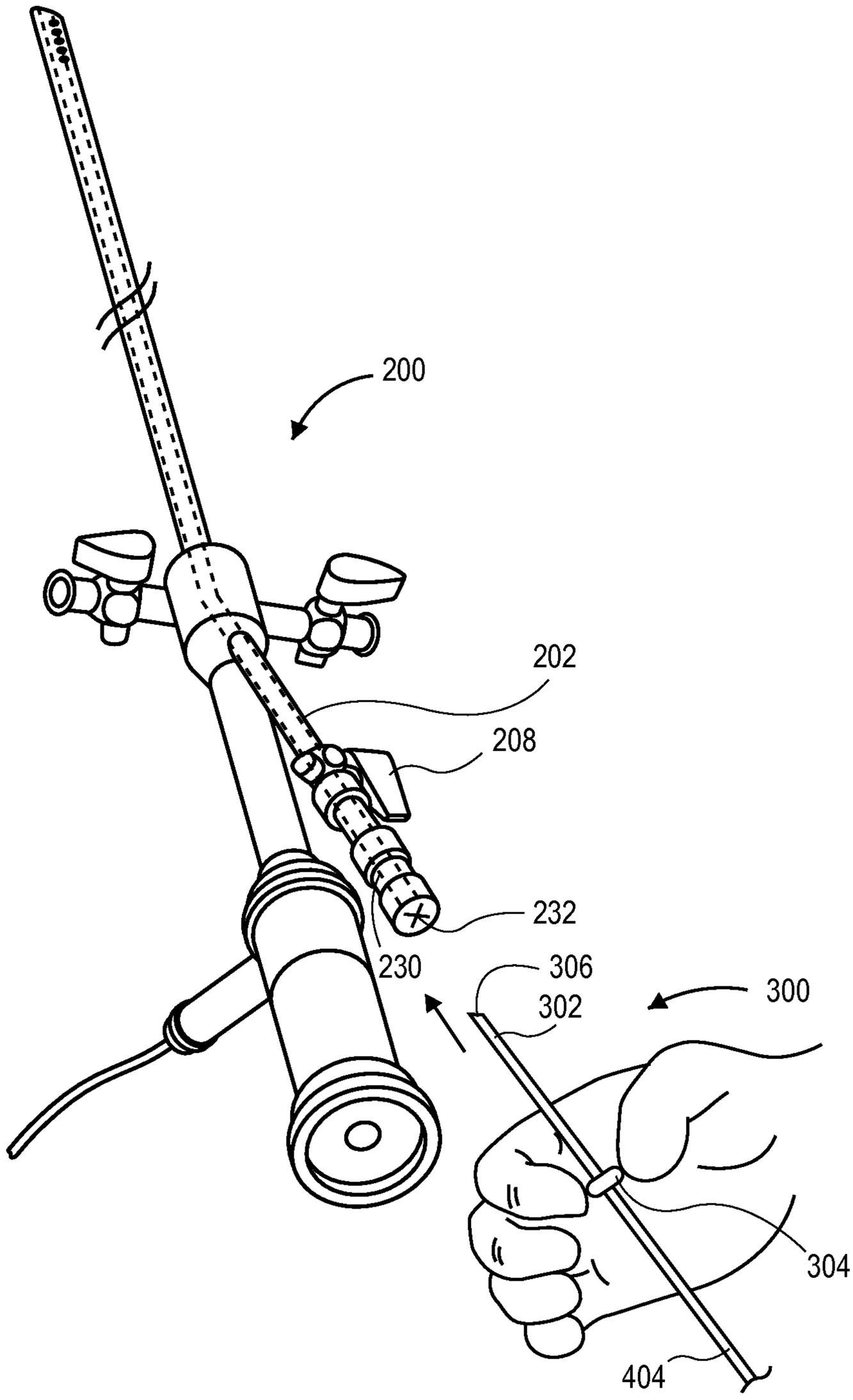

FIG. 12A

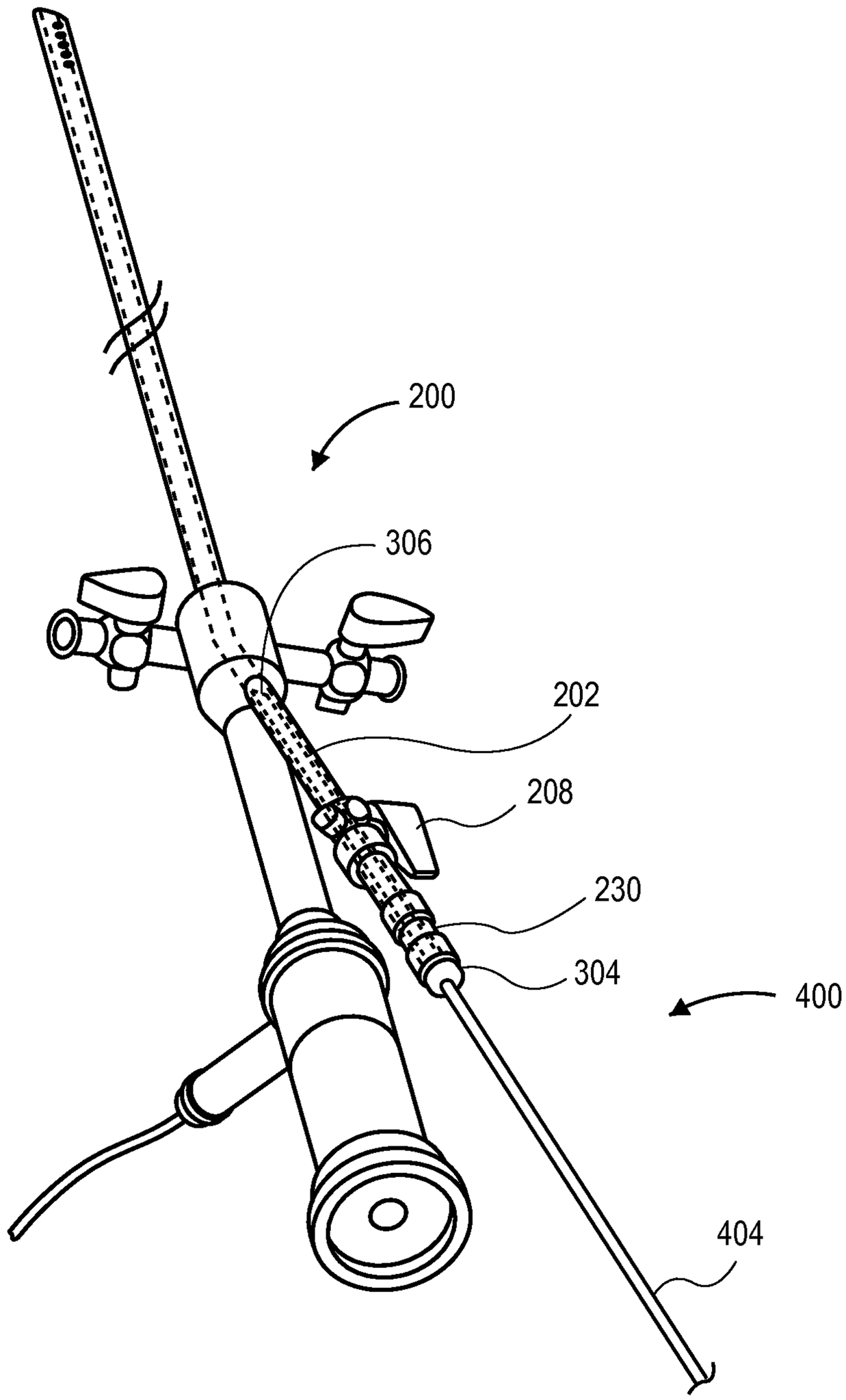

FIG. 12B

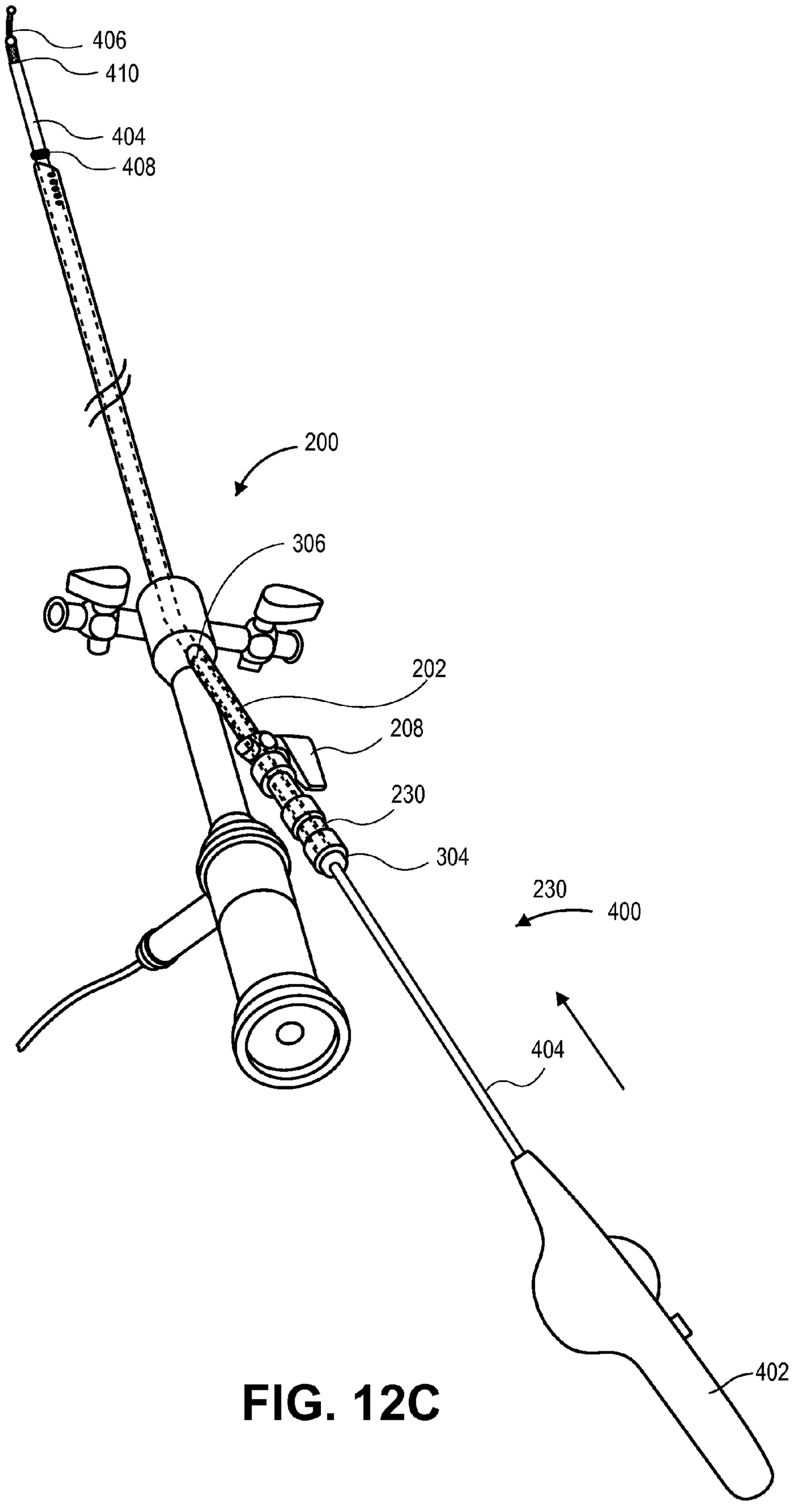

FIG. 12C

TIP PROTECTOR SLEEVE

BACKGROUND

Embodiments of the present invention relate to the field minimally invasive surgical medical devices and medical procedures. More specifically, embodiments of the present invention relate to devices and methods used for transcervical gynecological procedures.

Female contraception and sterilization may be affected by transervically introducing an object into a fallopian tube to inhibit conception. Devices, systems and methods for such a contraceptive approach have been described in various patents and patent applications assigned to the present assignee. For example, U.S. Pat. Nos. 6,526,979, 6,634,361, U.S. patent application Ser. No. 11/165,733 published as U.S. Publication No. 2006/0293560 and U.S. patent application Ser. No. 12/605,304 describe transcervically inserting an insert (also referred to as implant and device) into an ostium of a fallopian tube and mechanically anchoring the insert within the fallopian tube. One example of such an assembly is known as "Essure"® from Conceptus, Inc. of Mountain View, Calif. Tissue in-growth into the "Essure"® insert provides long-term contraception and/or permanent sterilization without the need for surgical procedures.

The insert may be delivered to the fallopian tube with a delivery catheter assembly such as the one illustrated in FIG. **1**. The delivery catheter assembly **100** is formed of a control device **102** such as a handle, an elongated sheath **104**, and an insert **106**. The delivery catheter assembly **100** may be transcervically positioned into the uterus and the fallopian tubes via a hysteroscope system.

Referring to FIG. **2** the hysteroscope system **200** may include a working channel **202** into which the delivery catheter assembly is inserted. Advancement of the delivery catheter system within the uterus and the fallopian tubes is usually facilitated by distending the uterus with a distention fluid, such as saline, and viewing the placement with the hysteroscope system. A valve clamp **208**, such as a ball valve clamp, and an access port **206** are positioned at the tip of the working channel **202**. Closing the valve clamp **208** may seal the entrance of the working channel **202** to prevent a distention fluid from leaking out of the access port **206**. A sealing cap **230** including a pierceable end **232** can be placed over the access port **206** to prevent distention fluid from leaking out of the hysteroscope system when a delivery catheter assembly occupies the working channel of the hysteroscope system.

An introducer **220** may be used in order to prevent damaging the tip the elongated sheath **104** or insert **106** of the delivery catheter assembly **100** during insertion through the pierceable end **232** of the sealing cap **230** and access port **206**, and into the working channel **202** of the hysteroscope system **200**. Introducer **220** includes a sheath portion **222** and slit opening **224** to aid in grasping and in the removal of the introducer **220**. The introducer **220** is inserted through the pierceable end **232** of the sealing cap **230** and into the working channel **202** prior to inserting the delivery catheter assembly **100**. When the introducer **220** is inserted through the sealing cap **230**, fluid can spray out of the introducer **220** and onto the physician or physician's assistant. The amount of fluid spray-back can be significant depending on the distention fluid pressure during the procedure.

Referring to FIG. **3**, after placing the introducer **220** into the working channel **202**, the tip of delivery catheter assembly **100** is inserted into the slit opening **224** and through the sheath **222** of the introducer **220** in order to advance the delivery catheter assembly **100** into the working channel **202**

of the hysteroscope system. This is typically performed as soon as possible after placement of the introducer **220** into the working channel **202** in order to minimize the amount of fluid spray-back from the introducer. The introducer **220** may then be removed or may be kept in place throughout the procedure. After insertion of the delivery catheter assembly **100** into the introducer **200**, an amount of distention fluid may still leak from between the introducer and elongated sheath **104** of the delivery catheter assembly **100**.

SUMMARY

Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system for accessing a female reproductive system. While embodiments of the invention are described with reference to a hysteroscope system, it is understood that the embodiments are not limited to such and may also be compatible with other optical surgical devices. In one aspect, embodiments of the invention describe a tip protector sleeve which functions as an introducer and protects the tip of a delivery catheter assembly when piercing a sealing cap, as well as during insertion through an access port, into the working channel and past a valve clamp of a hysteroscope system. In another aspect, embodiments of the invention describe a method and system which may reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system.

One embodiment of the present invention relates to a delivery catheter assembly which may be used to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may include a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. The tip protector sleeve may be locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath. For example, the interference stop may include a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. The male interference part may be fixed to the elongated catheter sheath, and the tip protector sleeve may comprise the female interference part. The tip protector sleeve may additionally incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into the working channel of a hysteroscope system

Another embodiment of the present invention relates to a method of forming a delivery catheter assembly which includes sliding a tip protector sleeve over a distal end of an elongated catheter sheath and toward a control device, and then fixing a bump onto a distal region of the elongated catheter sheath. Alternatively, the bump may be fixed onto the distal region of the elongated catheter sheath, and then the tip protector sleeve is slid over a proximal end of the elongated catheter sheath toward the bump prior to attaching the control device to the elongated catheter sheath. The control device may prevent the tip protector sleeve from sliding off a proximal end of the elongated sheath and define, in part, a proximal-stop position. The bump may prevent the tip protector sleeve from sliding off of a distal end of the elongated catheter sheath and define, in part, a distal-stop position. In an embodi-

ment, the bump may be fixed onto a distal region of the elongated catheter sheath by crimping a band onto the elongated catheter sheath. It is not necessary to crimp the entire length of the band, and only a proximal end of the band is crimped onto the elongated catheter shaft in an embodiment.

Another embodiment of the present invention relates to a method of delivering an insert into a body lumen such as an ovarian pathway (e.g. a fallopian tube) of a female body. Utilizing a delivery catheter assembly in accordance with embodiments of the invention the tip protector sleeve is positioned at the distal-stop position, and the tip protector sleeve is inserted through a pierceable end of a sealing cap, through an access port of a hysteroscope system and into a working channel of the hysteroscope system. In accordance with embodiments of the invention, the distal end of the elongated catheter sheath and insert are inserted through the pierceable end of the sealing cap, through the access port and into the working channel of the hysteroscope system simultaneously with the tip protector sleeve in the distal-stop position. The distal end of the elongated catheter sheath and insert may then be advanced through the tip protector sleeve and beyond the hysteroscope system to a target location within the body lumen where the insert is deployed within the body lumen. In an embodiment, the tip protector sleeve is advanced through the sealing cap into the working channel until a flanged mechanical stop, such as a bead or flared portion, abuts the sealing cap (or access port if a sealing cap is not utilized) prior to advancing the elongated sheath and insert to the target location.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional side view illustration of a delivery catheter assembly.

FIG. **2** is an isometric view illustration of a hysteroscope system and an introducer.

FIG. **3** is an isometric view illustration of a delivery catheter assembly inserted into an introducer and working channel of a hysteroscope system.

FIG. **4** is a side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

FIG. **5**A is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a proximal-stop position in accordance with an embodiment of the invention.

FIG. **5**B is a side view illustration of a delivery catheter assembly with a flanged mechanical stop of a tip protector sleeve in a cavity of a control device in accordance with an embodiment of the invention.

FIG. **5**C is a side view illustration of a delivery catheter assembly with a tip protector sleeve fastened into the proximal-stop position by a friction fitting in accordance with an embodiment of the invention.

FIG. **5**D is a side view illustration of a delivery catheter assembly with a tip protector sleeve screwed into the proximal-stop position in accordance with an embodiment of the invention.

FIG. **6** is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a distal-stop position in accordance with an embodiment of the invention.

FIG. **7** is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention

FIG. **8** is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention

FIG. **9** is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

FIG.**10** is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

FIGS. **11**A-**11**C are cross-sectional side view illustrations of tip protector sleeves incorporating various sealing valves in accordance with embodiments of the invention.

FIGS. **12**A-**12**C are isometric view illustrations of inserting a delivery catheter assembly into a working channel of a hysteroscope system in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system or other optical surgical device for accessing a female reproductive system. Various embodiments and aspects will be described with reference to details discussed below and the accompanying drawings will illustrate the various embodiments. The following description and drawings are illustrative of the invention and are not to be construed as limiting the invention. Numerous specific details are described to provide a thorough understanding of various embodiments of the present invention. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present invention.

In an embodiment, a delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. Referring to the FIG. **4** the tip protector sleeve **300** may include an elongated shaft **302**, a flanged mechanical stop **304** at a proximal end, and a distal end **306**. The distal end **306** can be flat or angled to assist with piercing of a sealing cap. In an embodiment, the distal end **306** has an approximately **45** degree angled tip. Elongated shaft **302** may be formed of a material and to a thickness which can be molded and does not buckle when piercing a sealing cap. For example, elongated shaft **302** may be formed of a material such as polyether ether ketone (PEEK).

Flanged mechanical stop **304** may provide variety of functions, be formed of a variety of materials and have a variety of shapes and sizes as will be explained in further detail with regard to FIGS. **5**A-**12**C. For example, flanged mechanical stop **304** may be formed of a moldable material such as polycarbonate, or from the same material as the elongated shaft **302**. Flanged mechanical stop **304** may be sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve **300** into the working channel. Flanged mechanical stop **304** may also be sized and shaped to be gripped by an operator's hand to assist with sliding of the tip protector sleeve **300** over a length of the elongated catheter sheath **404** of a catheter assembly. In this respect, one function may be as a handle at the proximal end of the tip protector sleeve **300**. Flanged mechanical stop **304** may also incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into a working channel.

Referring to FIGS. **5**A-**6**, a delivery catheter assembly **400** in accordance with embodiments of the invention is illustrated in which the tip protector sleeve **300** is locked onto and slideable over a length of the elongated catheter sheath **404**.

The delivery catheter assembly **400** may be formed by sliding a tip protector sleeve **300** over a distal end of an elongated catheter sheath **404** and toward a control device **402**, and then fixing a bump **408**AC onto a distal region of the elongated catheter sheath **404**. Alternatively, the bump **408** may be fixed onto the distal region of the elongated catheter sheath **404**, and then the tip protector sleeve **300** is slid over a proximal end of the elongated catheter sheath **404** toward the bump **408** prior to attaching the control device **402** to the elongated catheter sheath **404**. The control device **402** may prevent the tip protector sleeve **300** from sliding off a proximal end of the elongated sheath **404** and define, in part, a proximal-stop position. The bump **408** may prevent the tip protector sleeve **300** from sliding off of a distal end of the elongated catheter sheath **404** and define, in part, a distal-stop position. An operator may grip the flanged mechanical stop **304** by hand, for example between a thumb and index finger, and slide the tip protector sleeve over the elongated catheter sheath **404** between the proximal-stop and distal-stop positions.

FIG. **5**A is an illustration of the tip protector sleeve **300** positioned at a proximal-stop position. In the embodiment illustrated in FIG. **5**A, the flanged mechanical stop **304** abuts a distal end of the control device **402**, though other proximal-stop positions along the elongated catheter sheath **404** are contemplated in accordance with embodiments of the invention. For example, FIGS. **5**B-**5**D are illustrations of embodiments in which the control device **402** is configured to allow flanged mechanical stop **304** to slide within a cavity **420** located at a distal portion of the control device **402**. Such embodiments may be useful during operation in order to utilize the full working length of the elongated catheter sheath **404**. In this manner, the distal end of the control device **402** can be advanced to abut the access port **206** of the hysteroscope system or the pierceable end **232** of a sealing cap **230** if desired during operation. Alternatively, the distal end of the control device **402** can be advanced over the access port **206** of the hysteroscope system or over sealing cap **230** and the flanged mechanical stop **304** is allowed to abut the access port **206** or the pierceable end **232** of the sealing cap **230**. As illustrated in FIG. **5**B, flanged mechanical stop **304** may be slid into cavity **420** to abut a back wall **422** of the cavity at the proximal-stop position. Flanged mechanical stop **304** may be also configured to fasten onto the handle **402** at the proximal-stop position. For example, FIG. **5**C is an illustration of an embodiment in which flanged mechanical stop **304** may be slid into cavity **420** and fastened into the proximal-stop position by a friction fitting with sloped walls **424** of the cavity. FIG. **5**D is an illustration of an embodiment in which flanged mechanical stop **304** may be screwed into cavity **420** in which threads **330** on flanged mechanical stop **304** mate with threads **430** inside cavity **420** to fasten tip protection sleeve **300** in the proximal-stop position. In an embodiment, a suitable fastening mechanism for fastening tip protector sleeve **300** onto control device **402** is able to hold the tip protector sleeve **300** in the proximal-stop position during withdrawal of the delivery catheter assembly **400** from the working channel of the hysteroscope system.

Referring now to FIG. **6** an operator may slide the tip protector sleeve over the elongated catheter sheath **404** between the proximal-stop position and the distal-stop position illustrated in FIG. **6**. As illustrated, the distal end **306** of tip protector sleeve **300** may extend distally beyond a distal end of the elongated catheter sheath **404** and insert **406** when at the distal-stop position. In this manner, the tip protector sleeve **300** may protect the distal ends of the elongated catheter sheath **404** and insert **406** during piercing of a sealing cap and during insertion into the working channel and past a valve clamp of the hysteroscope system.

An interference stop may determine the distal-stop position and prevent the tip protector sleeve **300** from sliding off of the distal end of the elongated catheter sheath **404**. In an embodiment, the interference stop includes a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. Referring again to FIG. **5**A, the male interference part may comprise a bump **408** fixed to the elongated catheter sheath **404**. Bump **408** may be formed along only a portion of the circumference of the elongated sheath, or may encircle the circumference of the elongated sheath. In an embodiment, bump **408** is a band fixed to and encircling the circumference of the elongated catheter sheath. In an embodiment, bump **408** is fixed to the elongated catheter sheath **404** with a sufficient shear strength to ensure that the tip protector sleeve may be removed from a working channel of a hysteroscope system along with removal of the elongated catheter sheath **404**.

FIG. **7** is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. FIG. **8** is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. As illustrated in FIGS. **7**-**8**, flanged mechanical stop may be a bead **304**A having a barrel-like shape, though embodiments of the invention are not limited to such a shape. In an embodiment, bead **304**A is fixed to shaft **302** with an adhesive.

Referring to FIG. **8**, in an embodiment bead **304**A may be fixed to a proximal end of the elongated shaft **302**. Bead **304**A may include a distal portion **308** surrounding the proximal end of the elongated shaft **302**, a shoulder portion **310** extending proximally of the elongated shaft **302**, and a backstop **312**. The distal portion **308** may be fixed to the elongated shaft **302** with an adhesive. In an embodiment, the backstop **312** abuts the proximal end of the elongated shaft **302**. Backstop **312** may also have a height which is greater than a thickness of the elongated shaft **302**. For example, the height may be defined as the distance between and inside diameter (ID) of the backstop and an ID of the distal portion **308** of the bead **304**A. In accordance with various embodiments of the invention, the dimensions and location of the backstop **312** as they relate to the dimensions and location of bump **410** create an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath **404**.

In an embodiment, the tip protector sleeve **300** is locked onto an "Essure"® delivery catheter assembly. In such an embodiment, the ID of elongated catheter sheath **404** may be between 0.0405 and 0.0420 inches and the outside diameter (OD) of elongated catheter sheath **404** may be between 0.0538 and 0.0560 inches. Elongated catheter sheath **404** may be formed of a polyether block amide also known under the trade name PEBAX. The OD of elongated catheter sheath **404** may be used to determine the ID of bump **408**. In an embodiment, bump **408** may have an ID between 0.0545 and 0.0555 inches and an OD between 0.0575 and 0.0580 inches. In one embodiment, the ID of bump **408** may be smaller than the OD of the elongated catheter sheath **404**. In another embodiment, the OD of the elongated catheter sheath **404** is smaller than the ID of bump **408**. For example, the OD of the elongated catheter sheath **404** may be between 0.0538 and 0.0542 inches.

Bump **408** may be a band that is fixed to and encircles the elongated catheter sheath. Bump may be fixed to the elongated catheter sheath **404** by a variety of mechanisms includ-

ing adhesive and crimping. In an embodiment, bump **408** is formed of a material which is strong enough to resist deformation during operation of the delivery catheter assembly, yet malleable enough to be suitable for crimping. For example, stainless steel possesses suitable strength and malleability. In an embodiment, only a distal end **410** of the band is crimped onto the elongated catheter sheath, as illustrated in FIG. **8**. This leaves the proximal end, with the original OD between 0.0575 and 0.0580 inches to act as the male interference part which interferes with the ID of backstop **312** functioning as a part of the female interference part. While an embodiment of bump **408** is described in detail in FIG. **8** in operable relationship with bead **304**A, it is understood that bump **408** can be in operable relationship with other flanged mechanical stops, such as those illustrated in FIGS. **9-11**C.

Still referring to FIG. **8**, bead **304**A may be formed of a variety of materials and have a variety of shapes and sizes to perform a variety of functions. In one aspect, bead **304**A may be sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve **300** into the working channel. In one aspect, bead **304**A may perform the function as a handle for gripping by the operator. In another aspect, bead **304**A may include a backstop **312** which functions as part of the female interference part. In an embodiment, bead **304**A has an OD of approximately 0.112 inches. The distal portion **308** of bead **304**A may have an ID of approximately 0.070 and may be bonded to the OD of elongated shaft **302**. Backstop **312** may have an ID which is smaller than an OD of the proximal end of bump **408**. For example, backstop **312** may have an ID between 0.0565 and 0.0575 inches. In such an embodiment, backstop **312** has a height that extends from the ID of back stop **312** to the ID of the distal portion **308** of the bead **304**, or approximately 0.013 inches.

In accordance with embodiments of the invention tip protector sleeve **300** may be locked onto the delivery catheter assembly **400**. Shaft **302** may be used to pierce a sealing cap and protect the tip of the insert **406**, elongated catheter sheath **404** or guidewire during insertion into the working channel and past a valve clamp of a hysteroscope system. In an embodiment, the shaft **302** and elongated catheter sheath **404** may be advanced into a working channel of a hysteroscope system without allowing a significant amount of fluid (e.g. saline) spray-back or leakage from the delivery catheter assembly. The elongated catheter sheath **404** may additionally be slid through the shaft **302** to deliver the insert **406** to a body lumen, while the delivery catheter assembly **400** does not allow a significant amount of fluid leakage. Referring now to FIG. **12**A, the shaft **302** may pierce the pierceable end **232** of a sealing cap **230** with the tip of the shaft **306**. The outside diameter of the shaft **302** may fit tightly in the pierceable end **232** effectively creating a water tight seal between the sealing cap **230** and tip protector sleeve **300**.

The reduction of fluid spray-back and leakage may also be achieved by controlling the shape and dimensions of the tip protector sleeve **300** as it interacts with the elongated catheter sheath **404** and bump **408**. In an embodiment, shaft **302** may be approximately 2.82 inches long from the proximal end to the distal end of the tip **306**, which may be angled. Shaft **302** may have an ID between 0.0585 and 0.0605 inches and an OD between 0.0690 and 0.0710 inches. The shaft **302** ID may be selected to not allow for fluid to flow proximally between the shaft **302** and elongated catheter sheath **404** (and bump **408**), while still allowing for the elongated catheter sheath **404** to slide and be advanced through the shaft **302**. In such and embodiment, a minimum clearance between the ID of the elongated shaft **302** (e.g. 0.059 inches) and the OD of the elongated catheter sheath **404** (e.g. 0.055 inches) provides sufficient resistance to spray-back and leakage. Such a minimum clearance may be effective for overlapping constant diameters of the elongated shaft **302** and elongated catheter sheath **404**.

Referring now to FIG. **9**, an embodiment for tip protector sleeve **300**B is illustrated. As illustrated in FIG. **9**, tip protector sleeve **300**B includes an elongated shaft **302**, a bead **304**B and inner shaft **320**. Tip protector sleeve **300**B operates similarly as tip protector sleeve **300** with one difference being that backstop **322** is the distal end of inner shaft **320**. In such an embodiment, the shape and dimensions of tip protector sleeve **300**B are controlled so that bump **408** interferes with movement of the distal end, backstop **322** of inner shaft **320**. In such an embodiment, bead **304**B may be sized and shaped to act as a stop mechanism that controls the insertion depth of the tip protector sleeve **300**B into the working channel and may perform the function as a handle for gripping by the operator

Referring now to FIG. **10**, another embodiment for tip protector sleeve **300**C is illustrated. As illustrated in FIG. **10**, tip protector sleeve **300**C includes an elongated shaft **302**, a neck portion **332**, and a flared portion **304**C. Tip protector sleeve **300**C operates similarly as tip protector sleeves **300** and **300**B. One difference is that the neck portion **332** operates as the backstop for bump **408**. The neck portion **332** may be integrally formed with the elongated shaft **302** or be a separate member bonded to the inside diameter of elongated shaft **302** Likewise flared portion **304**C may be integrally formed with the elongated shaft **302** or be a separate member bonded to the outside diameter of elongated shaft **302**. In such an embodiment, flared portion **304**C may be sized and shaped to act as a flanged mechanical stop that controls the insertion depth of the tip protector sleeve **300**C into the working channel and may perform the function as a handle for gripping by the operator.

Embodiments of the invention are also envisioned in which the elongated catheter sheath **404** does not have a constant OD along its length. In accordance with some embodiments, the tip protector sleeve **300** may include a change in ID or a valve to accommodate variations in the OD of the elongated catheter sheath **404**, or to more effectively seal an elongated catheter sheath **404** with a constant OD. Referring again to FIG. **9**, inner shaft **320** is illustrated as having a smaller ID than the ID of elongated shaft **302**. In addition to functioning as an interference part, the ID of inner shaft **320** may more effectively accommodate a reduction in OD of the elongated catheter sheath **404**. Referring again to FIG. **10**, the ID of neck portion **332** may also more effectively accommodate a reduction in OD of the elongated catheter sheath **404** in addition to functioning as an interference part. Thus, a minimum clearance between the ID of inner shaft **320** or ID of neck portion **332** and the OD of the elongated catheter shaft **404** may provide enhanced resistance to fluid-spray back.

FIGS. **11**A-**11**C are illustrations embodiments of a tip protector sleeve incorporating various sealing valves to reduce the amount of fluid spray-back and leakage between the tip protector sleeve and elongated sheath of the delivery catheter assembly. While illustrated separately, it is understood that the embodiments illustrated in FIGS. **11**A-**11**C may be combined with other embodiments of the invention. More specifically, any of the sealing valves described in reference to the illustrations in FIGS. **11**A-**11**C may be combined with any of the embodiments further describing the proximal-stop and distal-stop positions.

FIG. **11**A is an illustration of a tip protector sleeve **300**D including an elongated shaft **302**, a housing **304**D, and valve **340**. Housing **304**D may function as a stop mechanism that controls the insertion depth of the tip protector sleeve **300**D into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft **302** may be coupled to a distal tip **342** of the housing **304**D which may function as a backstop for interference with a bump **408** fixed to the elongated catheter sheath **404** at the distal-stop position. Housing **304**D additionally houses valve **340** which is capable of accommodating multiple variations in OD of the elongated catheter sheath **404**. For example, valve **340** may be a silicone valve containing a slit at the distal end that allows for a catheter shaft to pass through it. The silicone material may allow for the slit to conform to different shapes or diameters while providing a seal. Due to the geometry on the distal end of the silicone valve, as fluid tries to pass from distal to proximal, the end of the valve may be pushed closed due to a chamfer on the end of the valve.

FIG. **11**B is an illustration of a tip protector sleeve **300**E including an elongated shaft **302**, a housing **304**E, and a compression valve **350** including an screw cap **354** which may be threaded down onto an O-ring **352** to compress it against the elongated catheter sheath **404**. Housing **304**E may function as a stop mechanism that controls the insertion depth of the tip protector sleeve **300**E into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft **302** may be coupled to a distal tip **342** of the housing **304**E which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

FIG. **11**C is an illustration of a tip protector sleeve **300**F including an elongated shaft **302**, a housing **304**F, and a compression valve **360** including a cap **362**, a compression spring **364** and a thin walled tube (not illustrated) inside the housing. For example, the thin walled tube may be made of a material such as silicone. Threads between the cap **362** and the housing **304**F apply a twist motion to the tube. When the tube is twisted, an inner diameter of the tube tightens like an iris. The compression spring **364** keeps the cap **362** extended and the threads hold the twist or keep the iris closed. When the cap **362** is pushed towards the housing **304**F (spring compressed) the cap **362** untwists and the iris opens. In this manner the opening of the iris can be adjusted based upon the OD of the elongated catheter sheath **404**. Similar to tip protector sleeves **300**D and **300**E, housing **304**F may function as a stop mechanism that controls the insertion depth of the tip protector sleeve **300**F into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft **302** may be coupled to a distal tip **342** of the housing **304**F which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

A delivery catheter assembly in accordance with embodiments of the invention may be utilized to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may protect the tip of an elongated catheter sheath, guidewire, or insert during piercing of a sealing cap and insertion into the working channel and past a valve clamp of a hysteroscope system and reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system. In an embodiment, the delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an insert releasably disposed within the elongated catheter sheath. In an embodiment, the insert extends distally beyond the elongated catheter sheath. In an embodiment, the insert includes a preformed bend, as illustrated in FIG. **5**, which may be utilized to assist with navigation through a curved portion of a fallopian tube. Upon providing the delivery catheter assembly the operator may grasp a flanged mechanical stop **304** or other suitable portion of the tip protector sleeve **300** to position the tip protector sleeve at the distal-stop position illustrated in FIG. **6**. If a sealing valve is present on the tip protection sleeve **300**, the sealing valve may then be tightened onto the elongated catheter sheath **404** if necessary to provide an optimal seal to protect against fluid spray-back and leakage.

Referring now to FIGS. **12**A-**12**C, the operator may then pierce a pierceable end **232** of a sealing cap **230** with the tip protector sleeve **300** and insert the tip protector sleeve **300** through an access port **206** of a hysteroscope system **200** and into the working channel **202** of the hysteroscope system. During insertion the tip protector sleeve **300** may be advanced past a valve clamp **208** of the hystero scope system. The tip protector sleeve protects against the possibility of the exposed portion of the insert **406** from catching on the valve clamp **208** and compromising the insert integrity. In accordance with embodiments of the invention, the distal end **410** of the elongated catheter sheath **404** and insert **406** are inserted through the sealing cap **230** and access port **206**, and into the working channel **202** of the hysteroscope system simultaneously with the tip protector sleeve **300** in the distal-stop position. The simultaneous insertion of the tip protector sleeve **300** and elongated catheter sheath **404** may avoid a problem of fluid spray-back associated with sequentially inserting an introducer followed by an elongated catheter sheath. In an embodiment, the tip protector sleeve **300** may be advanced into the working channel simultaneously with the elongated catheter sheath and insert **406** until the flanged mechanical stop **304** abuts against the access port **206** or sealing cap **230**, if present, as illustrated in FIG. **12**B.

The distal end **410** of the elongated catheter sheath **404** may then be advanced past the hysteroscope system **200** as illustrated in FIG. **12**C, and onto a target location with the body lumen. The insert **406** may then be deployed into the body lumen. Depending upon operator preference, the tip protector sleeve **300** may remain inserted in the working channel **202** during the elongated catheter sheath **404** advancement and insert **406** deployment procedures or removed from the working channel **202**. In accordance with many embodiments of the invention it is understood that the tip protector sleeve **300** is permanently locked onto the elongated catheter sheath. It is also contemplated that the tip protector sleeve **300** could be removed from the catheter assembly after initially advancing the catheter assembly into the working channel, for example, by including a tear joint in the tip protector sleeve in which the tip protector sleeve can be manually torn off of the elongated catheter sheath by the operator.

In an embodiment, the insert **406** and distal end **410** of the elongated catheter sheath **404** are advanced to the target location within the body lumen while the flanged mechanical stop **304** on the tip protector sleeve **300** abuts the access port **206** or sealing cap **320**, if present. The amount of elongated catheter sheath **404** spanning between the flanged mechanical stop **304** and control device **402** may depend upon the procedure and patient's anatomy. It is envisioned that circum-

stances arise where the operator may wish to insert the entire available working length of the elongated catheter sheath **404** into the patient and advance the control device **402** all the way to the access port or sealing cap, if present. In accordance with embodiments of the invention illustrated in FIGS. **5**B-**5**D, this can be possible by including a cavity **420** in the control device **402** to accommodate the flanged mechanical stop **304**.

Once the insert **406** is deployed into the body lumen the delivery catheter assembly may be withdrawn from the working channel of the hysteroscope system. In one embodiment, during withdrawal of the delivery catheter assembly **400** from the working channel, the bump **408** on the elongated catheter sheath **404** may be withdrawn proximally against the backstop of the tip protector sleeve **300** and cause the tip protector sleeve **300** to be withdrawn from the working channel **202** of the hysteroscope system **200**. In another embodiment, the flanged mechanical stop **304** on the tip protector sleeve **300** can be fastened to the control device **402**. In this manner, during withdrawal of the delivery catheter assembly **400** from the working channel, the tip protector sleeve **300** remains fastened to the control device **402**.

In the foregoing specification, various embodiments of the invention have been described. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the invention as set forth in the appended claims. The specification and drawings are, accordingly, to be regarded in an illustrative sense rather than a restrictive sense. Hence, the scope of the present invention is limited solely by the following claims.

What is claimed is:

1. A delivery catheter assembly comprising:

a control device;

an elongated catheter sheath having a distal end and a proximal end connected to the control device;

a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath while locked onto the elongated catheter sheath; and

an interference stop comprising a male interference part fixed to the elongated catheter sheath at a first distance from the distal end of the elongated sheath, and a female interference part;

wherein the male interference part interferes with sliding of the female interference part over the elongated sheath such that the interference stop determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath, and the tip protector sleeve is longer than the first distance such that the tip protector sleeve extends distally beyond the distal end of the elongated catheter sheath when at the distal-stop position.

2. The delivery catheter assembly of claim **1**, wherein the tip protector sleeve comprises an elongated shaft and a backstop together functioning as the female interference part.

3. The delivery catheter assembly of claim **2**, wherein the male interference part comprises a bump fixed to the elongated catheter sheath.

4. The delivery catheter assembly of claim **3**, wherein the bump comprises a band fixed to and encircling the elongated catheter sheath.

5. The delivery catheter assembly of claim **4**, wherein a distal end of the band is crimped onto the elongated catheter sheath, and a proximal end of the band is not crimped onto the elongated shaft.

6. The delivery catheter assembly of claim **2**, wherein the backstop has an inside diameter which is smaller than an outside diameter of the male interference part.

7. The delivery catheter assembly of claim **6**, further comprising a molded bead fixed to a proximal end of the elongated shaft.

8. The delivery catheter of claim **7**, wherein the molded bead comprises:

a distal portion surrounding the proximal end of the elongated shaft;

a shoulder portion extending proximally of the elongated shaft; and

the backstop, wherein the backstop abuts the proximal end of the elongated shaft.

9. The delivery catheter assembly of claim **6**, wherein the tip protector sleeve further comprises an inner shaft fixed to a proximal end of the elongated shaft, and the backstop is a distal end of the inner shaft.

10. The delivery catheter assembly of claim **1**, further comprising an insert disposed within and extending distally beyond the distal end of the elongated catheter sheath, wherein the tip protector sleeve extends distally beyond the insert when at the distal-stop position.

11. The delivery catheter assembly of claim **1**, wherein the tip protector sleeve further comprises a sealing valve.

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